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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/711,847	10/08/2004	Alessandra Mazzeo	1673.01	5846
21901	7590	07/11/2007		
SMITH HOPEN, PA 180 PINE AVENUE NORTH OLDSMAR, FL 34677			EXAMINER YU, MELANIE J	
			ART UNIT	PAPER NUMBER
			1641	
			MAIL DATE	DELIVERY MODE
			07/11/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/711,847

Applicant(s)

MAZZEO ET AL.

Examiner

Melanie Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,5,7 and 8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3,4,6 and 9-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 October 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/11</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election of group II, claims 3-11, in the reply filed on 25 April 2007 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Applicant's further elect the species group of 8 rods with 12 small cylinders. Claims 1, 2, 5, 7 and 8 are withdrawn from being drawn to a non-elected invention.

### ***Claim Objections***

2. Claims 3, 4, 6 and 9-11 are objected to because of the following informalities: the limitations in parenthesis in the claims should be removed because it is unclear whether the limitations are intended to be part of the claim. The phrase "characterized by the fact" recited in the claims should be changed to "wherein" because it is unclear whether the characterized limitation is intended to further limit the claims. The phrase "the immunocomplexes" in line 4 of claim 3 lacks antecedent basis in the claims. The phrase "the sample" in line 6 of claim 3 lacks antecedent basis in the claims. The phrases "the specific conjugates" and "the chromogenous compound" recited in claim 3 lack antecedent basis in the claims.

Regarding claim 6, ninety0six should be changed to ninety-six.

Claim 10 recites "the card", "the identification code", "the container for samples" and "the cover or lid" and there is lack of antecedent basis for these limitations in the claims.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 3, 4, 6 and 9-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "blocked" in line 5 of claim 3 are vague because it is unclear whether blocked is referring to the cylinders being blocked by a chemical or physical entity or whether the term blocked is referring to the cylinders being fixed at a modular distance on the rod. The term small in claim 3 is vague because it is unclear what size is encompassed by the term small. Furthermore, it is unclear whether the claim intends to encompass the specific conjugates or chromogenous compound in the microwell, or whether the microwell must merely be capable of containing these compounds.

With respect to claim 4 it is unclear how the colored button indicates the direction of loading. It is vague as to whether a certain orientation of color or design is required to indicate the direction of loading or whether one side of the grill is colored so as to show the top side of the grill.

Regarding claim 9, the phrase "small colored squares" is unclear because it is vague as to what size square is encompassed by the term small.

With respect to claim 10, it is unclear how the card, identification cod is related to the container for samples or how the container for samples relates to the microwell or microplate. It is vague as to whether the container for samples is the microwell or whether it is a separate entity. It is further unclear as to how the cover or lid is related to the container, or the device of claim 3.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
1. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hubscher (US 5,494,830) in view of La Motte (US 5,882,595).

Hubscher teaches a device comprising small adsorbent cylinders (11, 12, 13; Fig. 1 and Fig. 3; test unit, col. 3, line 55- col. 4, line 2) on which immunocomplexes form (allergens or analyte adsorb onto the tip, col. 4, lines 35-53), wherein the small adsorbent cylinders are spaced at a modular distance on a rod (rod is support strip which holds the test unit which are the cylinders, col. 2, lines 41-48); and the rod carries a label to identify the sample under examination (col. 4, lines 5-9); wherein the rod is placed onto a support (rod is placed onto a support because support strips are used in an automated process and handled and supported with brackets 32 and 33, Fig. 1, and therefore is attached to a support, col. 4, lines 13-15; col. 4, lines 60-63) and the support is positioned above a plate furnished with wells with the wells placed at modular distances (reaction containers are wells placed at fixed distances from each other, col. 4, lines 54-60); and the small cylinders projecting from the rod are held by the support at the same modular distance at which the wells are placed (small cylinders are placed at the same distance as the wells, col. 4, lines 57-60); and the small cylinders, when the support is placed above the plate penetrate into

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the wells filled with specific conjugates (cylinders are the test units and are simultaneously inserted into the wells, col. 4, lines 60-63; plate, 75, and wells, 60, Fig. 1). Hubscher fails to teach the plate being a microplate, the wells being microwells and the rods being of a size that can penetrate a microwell.

La Motte teaches a device comprising a rod with attached comb teeth, that are placed onto a support (comb holder placed in comb rack, which is the support, comb is the rod with attached teeth that penetrate into wells, col. 4, lines 29-35) and the support is positioned above a microplate furnished with microwells, wherein the microwells placed at modular distances (microtiter plate for preparing samples, col. 5, lines 2-7; wells hold 20 or 100 microliters of liquid and are therefore microwells, and the plate containing the wells is considered a microplate, col. 2, lines 9-18), in order to provide wells that hold a required amount of liquid.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Hubscher, a microplate furnished with microwells and test units that fit into the microwells as taught by La Motte, in order to provide a more compact series of wells for sample detection.

With respect to claim 4, La Motte teaches a grill that is formed of at least two parallel vertical and horizontal sides with a handle (col. 3, lines 16-30), wherein there is a colored button on the grill that is capable of indicating the direction of loading (knob orients the loading of the comb member and is therefore capable of indicating the direction of loading and because it is an element of the device, also has a color, col. 3, lines 23-30).

Regarding claim 6, Hubscher teaches that a rod with 12 cylinders (11-22, Fig. 1, col. 4, lines 9-13) and La Motte teaches the comb rack being able to hold 8 rods (combs), (col. 3, lines 12-15). Although Hubscher in view of La Motte do not specifically teach a 96 well microplate, La Motte illustrates a 96 well microplate at reference letter A of Figure 15.

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Additionally, Hubscher in view of La Motte teach a device having 8 rods of 12 cylinders each and therefore it would have been obvious to use a 96 well plate with 8 columns and 12 lines to accommodate all the small cylinders of the device.

Claim 11 recites that the rods, cylinders, containers for samples and microstrips are constructed entirely for the carrying out of the test in the field or in non-specialist surgeries or laboratories, which is drawn to an intended use of the device and does not provide any further product limitations to the device. Since Hubscher in view of La Motte teach the required product limitations, and is therefore capable of performing the recited intended use.

2. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hubscher (US 5,494,830) in view of La Motte (US 5,882,595) further in view of Bojanic et al. (US 5,417,923) and Kobylecki et al. (US 6,153,375).

Hubscher in view of La Motte teach a device, wherein Hubscher specifically teaches that the plate is a strip in which the wells are present (60, Fig. 1, col. 4, lines 54-57), which would therefore be a microstrip with microwells when combined with La Motte and the small cylinders are color coded and correspond to a particular analyte (col. 5, lines 8-28), but fail to teach the wells distinguished by small colored squares.

Bojanic et al. teach that a 96 well microtiter plate with microwells may be labeled with numbers and letters (Fig. 1; col. 5, lines 3-18), in order to identify the sample in the microwells.

Kobylecki et al. teach that numbers, letters or colors may be used as labels (col. 5, lines 35-40), in order to provide labels for reaction zones.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Hubscher in view of La Motte, colored microwells as taught by Bojanic et al., in order to provide precise identification of

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samples in the containers. It would have further been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Hubscher in view of La Motte further in view of Bojanic et al., coloring labels instead of numbers and letters as taught by Kobylecki et al. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent labeling technique and since the same expected identification effect would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the preference and availability of labeling materials.

3. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hubscher (US 5,494,830) in view of La Motte (US 5,882,595) further in view of Justin et al. (US 2005/0089444).

Hubscher in view of La Motte teach a device with a rod and small cylinders having a bard code (col. 3, lines 50-53), but fail to teach a place to position a card bearing an identification card for the sample.

Justin et al. teach a card having a sample identification code that can be inserted into a specific holder that is capable of being inserted into a cover and an external site (external identification system that scans the codes on sample identification cards, par. 55), in order to provide efficient sample identification. Although Justin et al. do not specifically teach the capability of being inserted into a cover, such a limitation is drawn to intended use and does not appear to provide any further product limitations. Therefore since Justin et al. teach the required product limitations of the card, the card is capable of being inserted into a cover.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the device of Hubscher in view of La Motte, a



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sample identification card with an identification code as taught by Justin et al., in order to provide fast sample identification.

**Conclusion**

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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